

virus vector, such as a vector comprising a E1/E3 deletion. In particular aspects, the adenovirus vector is an adenovirus 5 vector. In yet further aspects the virus is an enveloped virus (e.g. influenza virus).

[0010] A heterologous antigen according to the embodiments can be any of variety of antigens, including but not limited to, a cancer cell antigen or an infectious disease antigen, such as a viral, bacterial or parasite antigen. In certain aspects, the heterologous antigen is a heterologous viral polypeptide, such as a viral envelope polypeptide. For example, the heterologous antigen may be an Ebola virus polypeptide, such as the Ebola virus glycoprotein. In some further aspects, the expression cassette encodes a heterologous antigen, which has been codon optimized for expression in mammalian (e.g., human) cells. Additional exemplary antigens for use according to the embodiments are detailed below.

[0011] In a further specific embodiment there is provided an immunogenic composition comprising a recombinant adenovirus vector comprising an expression cassette encoding a heterologous antigen, said recombinant virus vector formulated in a substantially solid carrier comprising from about 0.1% to 10% of a zwitterionic surfactant, said zwitterionic surfactant having a lipid group with a carbon chain of 13-30 carbon atoms. In a particular aspect, the antigen is an Ebola virus glycoprotein.

[0012] In yet a further embodiment, there is provided a method for providing an immune response in a mammal comprising obtaining a composition in accordance with the embodiments and aspects described above, which has been dispersed in a pharmaceutically acceptable liquid, and administering an effective amount of the dispersed composition to a mammal. In certain aspects, such a method comprises obtaining a composition in a substantially solid carrier and dispersing the composition in a pharmaceutically acceptable liquid (e.g., water). In some aspects, the administering comprises administering the dispersed composition to a mucosal tissue of the mammal. In certain aspects, the administering is by oral, sublingual, buccal or intranasal administration. In particular aspects, the pharmaceutically acceptable liquid is water or saline solution. In certain aspects, obtaining the composition comprises solubilizing the solid composition in an aqueous liquid such as by contacting the solid with the aqueous liquid and incubating the solid and aqueous liquid for certain period of time, e.g., 1 to 15 minutes.

[0013] In yet a further embodiment there is provided a method for providing an immune response in a mammal comprising obtaining a composition a recombinant virus vector (e.g., an adenovirus vector) in a pharmaceutically acceptable carrier, said carrier comprising: (i) PMAL-C16 or (ii) from about 0.1% to 10% of a zwitterionic surfactant, and administering an effective amount to the composition to a subject, wherein the subject has been previously exposed to a virus that cross reacts antigenically with the virus vector of the composition. Thus, in some cases, a subject for treatment according to the embodiments comprises antibodies (e.g., neutralizing antibodies) that bind to the recombinant virus vector. In certain specific aspects, the virus vector is an adenovirus 5 vector and the subject has been previously exposed to adenovirus 5. In further aspects, the virus (e.g., virus vector) of the composition is an influenza virus and the subject has been previously exposed to influenza virus. In a further embodiment there is a provided a method for pro-

tecting a viral vector from a pre-existing immune response in a subject comprising formulating the viral vector with an effective amount of a zwitterionic surfactant (e.g., PMAL-C16) and administering the formulated viral vector to the subject.

[0014] In yet still a further embodiment there is provided a method of making a stabilized immunogenic composition comprising formulating a solution comprising a recombinant virus vector (e.g., an adenovirus vector) in a pharmaceutically acceptable carrier, said carrier comprising: (i) PMAL-C16 or (ii) from about 0.1% to 10% of a zwitterionic surfactant, and then drying the solution to provide a stabilized immunogenic composition. In certain aspects, drying the solution comprises dispersing the solution in a thin film and allowing the liquid to evaporate. In further aspects, the method additionally comprises aliquoting an amount of the stabilized immunogenic composition into a container. In some aspects, prior to drying, the solution comprises about 0.1 to 50 mg/ml, 1 to 40 mg/ml, 1 to 30 mg/ml, 1 to 20 mg/ml, or 1 to 10 mg/ml of the zwitterionic surfactant. In other aspects, prior to drying, the solution comprises about 0.1 to 50 mg/ml, 1 to 40 mg/ml, 1 to 30 mg/ml, 1 to 20 mg/ml, or 1 to 10 mg/ml of PMAL-C16.

[0015] The present disclosure generally relates to vaccine compositions that may be administered to a subject via the buccal and/or sublingual mucosa. In some embodiments, the present disclosure also relates to methods for administration and preparation of such vaccine compositions.

[0016] In one embodiment, the present disclosure provides a composition comprising an antigen dispersed within an amorphous solid.

[0017] In another embodiment, the present disclosure provides a method comprising administering a vaccine composition comprising an antigen dispersed within an amorphous solid to the buccal and/or sublingual mucosa of a subject in an amount effective to induce an immune response to the antigen.

[0018] In yet another embodiment, the present disclosure provides a method comprising providing an antigen and a solution comprising a sugar, sugar derivative or a combination thereof; dispersing the antigen within the solution to form a mixture; and allowing the mixture to harden so as to form an amorphous solid.

[0019] The features and advantages of the present invention will be apparent to those skilled in the art. While numerous changes may be made by those skilled in the art, such changes are within the spirit of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Some specific example embodiments of the disclosure may be understood by referring, in part, to the following description and the accompanying drawings. The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0021] FIGS. 1A-1C: Multi-Component Formulations Improve Adenovirus Transduction Efficiency and Stabilize Virus in PLGA Microspheres. (1A) Transduction Efficiency of Excipients and Formulations in Differentiated Calu-3 Cells. Cell monolayers were exposed to formulations containing a model recombinant adenovirus serotype 5 vector expressing beta-galactosidase (AdlacZ) for 2 hours at 37° C. Transduction efficiency was determined by comparison of